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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,644	09/18/2003	Giuseppe Lombardo	ZL 0189	8511
23367	7590	03/08/2006	EXAMINER	
GENE WARZECHA LINVATEC CORPORATION 11311 CONCEPT BOULEVARD LARGO, FL 33773			SWIGER III, JAMES L	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/666,644	Applicant(s) LOMBARDO ET AL.	
	Examiner James L. Swiger	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 5-13 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to an apparatus/soft tissue anchor, classified in class 606, subclass 72.0.
- II. Claims 14-16, drawn to a method, classified in class 623, subclass 19.11.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the soft tissue anchor may be used with another process, such as in securing soft tissue to a knee.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Gene Warzecha on March 1, 2006 a provisional election was made without traverse to prosecute the inventions of groups I and II, claims 1-13 and 14-16, respectively. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

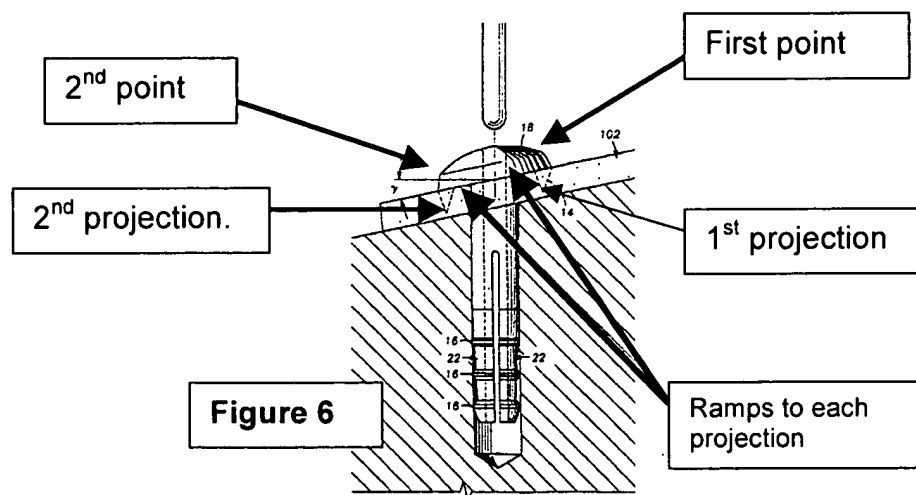
Information Disclosure Statement

No information disclosure statement was enclosed herein at the time of examination.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-9, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Torrie et al. (U.S. Patent No. 5,601,558). Torrie et al. disclose an invention of a soft tissue anchor having an elongated shaft (see Fig. 6 below), a bone engaging means (16), and a transverse head (see Figure 6 below) with a first and second points positioned a certain distance outward from the axis and a first and second projection positioned distally from the first and second points.



Torrie et al. also disclose a lumen (See Fig. 6 above) extending from the proximal (head of anchor) to the distal end, respective ramps going to the first and second projections (See Fig. 6 above), and a bone engaging means that is considered the outwardly extending barbs of the distal end of the anchor shown above (items 16 and 22, and also see Col. 4, lines 1-10).

With regards to claims 12 and 13 it should be noted that in addition to the bone engaging means noted in the paragraph immediately supra (the outward barbs), the distal projections may also be considered the tissue-engaging means capable of holding labral tissue adjacent to the glenoid fossa (See col. 3, lines 36-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torrie et al. '558 in view of Dudasik (U.S. Patent No. 6,648,893). Torrie et al. discloses the claimed invention except for a device having a transverse bottom surface that is arcuate between the first and second points, and also an arcuate distance subtended by a barb in a row being greater than that subtended by the immediately distally adjacent barb in that row. Dudasik teaches a transverse bottom surface that is arcuate between points (see area adjacent to 129 in Fig. 8) that allows for better engagement of the tissue and bone (Col. 5, lines 1-5) and an arcuate distance in its barbs, smaller in the

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distal direction, for a better fit to the bone (Col. 5, lines 11-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Torrie et al. having at least a transverse, arcuate bottom between the first and second points, and barbs subtended with respect to the ones distal in view of Dudasik to better secure the anchor to the bone.

With further regards to claim 10, Torrie et al. discloses the claimed invention except for an arcuate area that gets smaller towards the distal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the direction subtended barbs of Torrie et al. in view of Dudasik, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al. (U.S. Patent No. 5,720,766). Zang et al. discloses a soft tissue anchor having a shaft (44) with radially outwardly extending projections capable of being barbs (46) extending in longitudinal rows that are also capable of being a tissue engaging means towards the proximal end of the shaft (See Fig. 3).

Zang et al. does not disclose, however, barbs that have a smaller width in the direction of the distal end, for better securing the anchor into the bone. Dudasik discloses a device having barbs that vary in width allowing better attachment to the bone for more secure attachment of the anchor (Col. 5, lines 11-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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construct the device of Zang et al. having at least barbs with a longitudinally-varying width in view of Dudasik to better secure the anchor to the bone in use.

With further regards to claim 11, Zang et al. discloses the claimed invention except for a width area that gets smaller towards the distal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the direction subtended barbs of Zang et al. in view of Dudasik, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167

Allowable Subject Matter

Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 8:30am to 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLS

 3/2/2006


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER